An observational study to obtain normal values of inflammatory variables in induced sputum, exhaled breath, and bronchial biopsies from healthy smoking and non-smoking individuals

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ONDERZOEKSVRAAGSTELLINGEN1. Are differences with respect to markers of airway inflammation, lung function and symptoms between smokers and non-smokers of varying age?2. Which aspects of airway inflammation are associated with symptoms and lung...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Observational invasive

Summary

ID

NL-OMON33652

Source
ToetsingOnline

Brief title
The NORM study

Condition

- Bronchial disorders (excl neoplasms)

Synonym
Asthma, COPD, emphysema

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: KNAW hoogleraarschap Professor Postma

Intervention

Keyword: asthma, COPD, Inflammation, Smoking

Outcome measures

Primary outcome

Parameters for airway inflammation and remodeling in bronchial biopsies.

Secondary outcome

Parameters for airway inflammation in sputum and blood.

HRCT scan

symptoms

Lung function

Study description

Background summary

Smoking induces an inflammatory reaction in the airways which can ultimately result in persistent damage and the development of a Chronic Obstructive Pulmonary Disease (COPD). However, not all subjects who smoke end up with COPD. After long-term smoking, approximately 20% of subjects develop COPD. At this time, it is unclear why some subjects develop COPD, whereas others maintain a normal lung function.

In addition, smoking has important consequences in asthma. Patients with asthma who smoke have a more severe asthma and more often experience an asthma exacerbation. In addition, it has been shown that inhaled corticosteroids are less effective in smoking asthmatics.

With this research project, we will investigate the effects of smoking on the airways. To this end, we will compare markers of airway inflammation, lung function and symptoms between healthy smokers and non-smokers of varying age.

In addition, we will compare those healthy subjects with patients with asthma and COPD which are characterized in earlier studies.

Study objective

ONDERZOEKSVRAAGSTELLINGEN
1. Are differences with respect to markers of airway inflammation, lung function and symptoms between smokers
and non-smokers of varying age?
2. Which aspects of airway inflammation are associated with symptoms and lung function?
3. What is the effect of smoking on corticosteroid responsiveness (as can be investigated with laboratory techniques in
sputum and blood.
4. Are there differences with respect to the effects of smoking between healthy subjects and patients with asthma or COPD.
5. Is there a genetic difference between healthy smokers and smokers who have developed COPD.

Study design

This is an observational study. A total of 120 healthy subjects will be included, subdivided into 4 groups of 30 subjects each:
1. 30 individuals * 40 years, who currently smoke * 10 cigarettes/day and > 10
packyears.
2. 30 individuals * 40 years, who have not smoked during the last year, have never smoked for as long as a year (i.e. at least one cigarette per day
or
one cigar per week, AND have < 0.5 packyear.
3. 30 individuals above 40 years, who currently smoke * 10 cigarettes per day,
and > 20 packyears.
4. 30 individuals above 40 years, who have not smoked during the last year, have
never smoked for as long as a year, and have < 0.5 packyear.

These subjects will be extensively characterized with respect to symptoms, lung function parameters and inflammatory parameters in sputum, blood, and bronchial biopsies.

- Questionnaires (Asthma Control Questionnaire, Clinical COPD Questionnaire (CCQ), Asthma Control Questionnaire (ACQ), Co-Morbidity Questionnaire (ACE-27), Short QUestionnaire to Assess Health-enhancing Physical Activity (SQUASH).
- ECG.
- AGE reader.

- Spirometrie, CO diffusion.
- Induced sputum
- CO diffusion.
- Blood and urine.
- Bronchoscopy.
- Skin prick test.
- Measurement of exhaled NO.

Study burden and risks

This study is not associated with large risks. Possible adverse reactions may be:
- Blood collection may be painful and cause skin bruising.
- The provocation test with methacholine or AMP may cause temporary dyspnea.
- The HRCT scan of the lung is associated with radiation which may be harmful.
- The bronchoscopy may cause irritation of the airways and the bronchial biopsy may cause local bleeding.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Doctor*s diagnosis of normal pulmonary health
2. Post bronchodilator FEV1/FVC >70%
3. PC20 methacholine >12 mg/ml
4. Reversibility of FEV1% predicted <10%

Exclusion criteria

1. Persons who used inhaled or oral corticosteroids during >5 years, or within the last 5 years.
2. FEV1 <1.2 L,
3. A subject is not eligible to enter and participate if he does not agree that we inform his general practicioner about participation in the study and also about any unexpected finding during the study.
4. Upper respiratory tract infection (e.g. colds), within 2 months.
5. Pregnancy, or the possibility of being pregnant (i.e. women who do not use adequate anticonception as judged by the investigator).
6. Malignancy within the past 5 years (except for squamous or basal cell carcinoma of the skin that has been treated with no evidence of recurrence).
7. Signs or symptoms of any other concomitant disease that, in the eyes of the investigator, can interfere with the study results.
8. Known recent substance abuse (drug or alcohol).
9. Claustrophobia

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-07-2019
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT00848406
CCMO	NL26187.042.09